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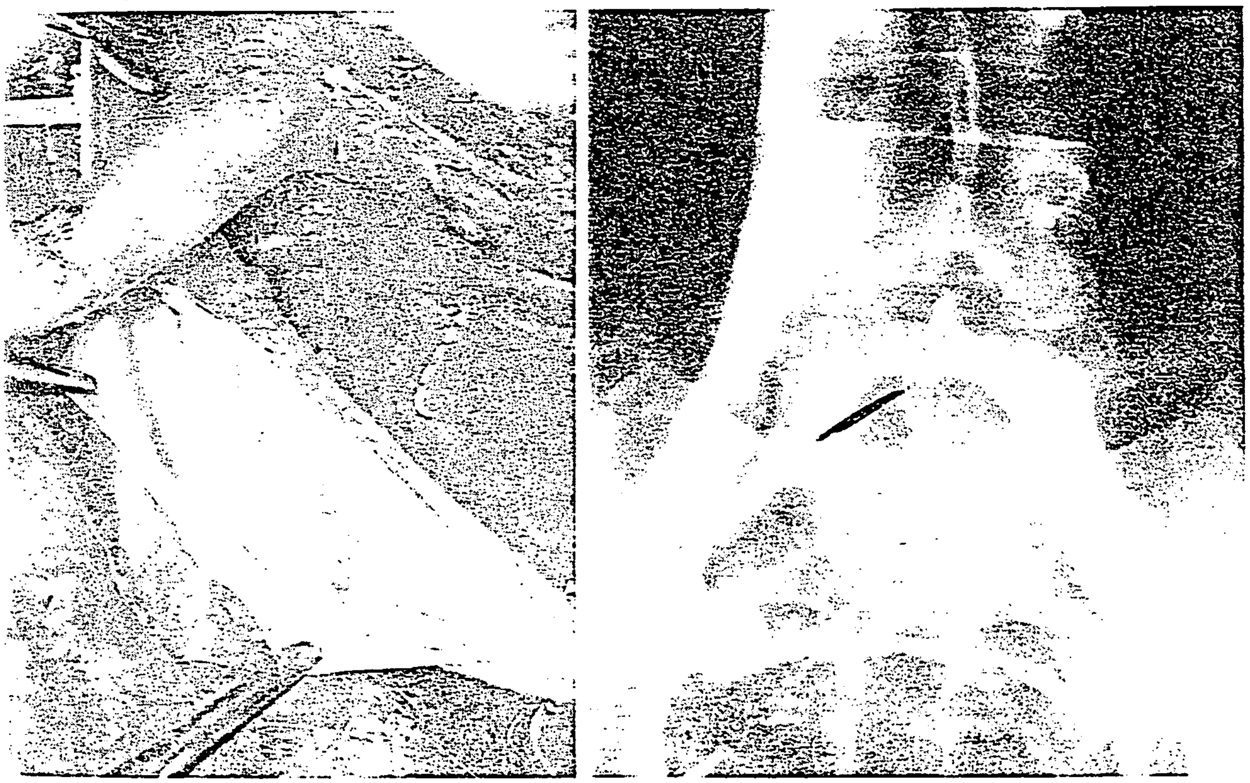

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Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire[1]

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A new type of endovascular prosthesis has been developed using a unique metal alloy (nitinol) with a heat-sensitive memory. Nitinol wire coil grafts were straightened in ice water and passed into the canine aorta *via* catheter, where they reformed into their original shapes. Follow-up aortograms demonstrated long-term patency with minimal thrombus formation. Nitinol endovascular coil grafts may eventually be used in the nonsurgical treatment of several forms of vascular disease.

Index terms: Catheters and catheterization, technique • Nitinol

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THE surgical replacement of a diseased artery with a tubular graft is an accepted and widely used procedure. The problem of thrombogenicity has to a large extent been solved by the use of porous synthetic graft material such as Dacron or Gore-tex (polyfluorotetraethylene).

Endoprostheses or tubular stents have been placed percutaneously in the biliary and urinary tracts to provide long-term patency of bile ducts or ureters (1). These nonporous plastic catheters, which are small in diameter, can be passed percutaneously and left in place without the risk of thrombosis such as occurs in the arterial system.

Small tubular prostheses made of various nonporous synthetic materials have also been placed intra-arterially; however, all have thrombosed. Coil spring grafts were less likely to thrombose, but only small coils could be passed percutaneously (2).

We have developed a new type of endoprosthesis, constructed of a thermal shape memory alloy (nitinol), which can be readily passed through a catheter. With this technique, a long-term arterial graft without thrombosis may be achieved. The method of introduction and preliminary results are discussed in this report.

Material and Methods

Animal Preparation

Four mongrel dogs weighing 15 to 30 kg were anesthetized with sodium pentobarbital (30 mg/kg), and a femoral artery cutdown was performed. An aortogram was obtained using a 7-F pigtail catheter (30 ml meglumine diatrizoate at 20 ml/sec) to assess the diameter of the abdominal aorta. One nitinol coil was introduced into the aorta of each dog.

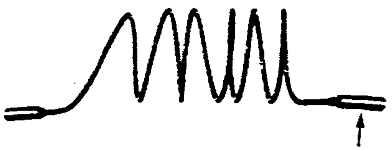
Preparation of the Endovascular Prosthesis

Nitinol is a specially formulated alloy of nickel and titanium that can be drawn into a wire of precise dimensions. The striking property of the alloy is that it undergoes a phase change at a certain temperature. The "transition temperature" is determined by the composition of the alloy. The wire is annealed at 525° C for 30 minutes while being constrained to a desired shape. After cooling, the wire can be straightened and introduced *via* catheter into the body. At or near body temperature the wire transforms into its original shape. This property of the wire allows one to introduce into the body various complex, preformed shapes *via* catheter.

We constructed four nitinol coils of varying dimensions by wrapping the wire (0.028" diameter) on stainless steel mandrels of different sizes (Fig. 1). The length of the coils ranged from 1 to 6 cm. Coil diameters ranged from 5 to 11 mm. Coil frequencies varied from closely wound (no space between turns of the coil) to loosely wound (one turn per centimeter). After annealing, the nitinol coils were straightened in a bath of sterile ice water and passed through a 10-F Teflon catheter in the abdominal aorta. The nitinol coils were fastened to a threaded guiding wire to allow accurate placement after being deposited in the aorta. To minimize transformation of the wire to its original shape in the catheter, a cold saline solution (10° C) was flushed continuously through the catheter during introduction of the wire.

Once the wire was extruded from the catheter, precise placement of the newly formed coil was accomplished by advancing or withdrawing the guide wire in the aorta. Detachment of the coil was achieved by unscrewing the guide wire from the distal end of the coil.

Figure 1



Loosely wound nitinol coil graft (diameter = 8 mm). Note threaded adaptor (arrow), which can be attached to a modified guide wire. The coil is straightened in ice water and passed *via* catheter into the aorta. The coil reforms when heated to body temperature and is positioned by moving the attached guide wire.

After coil placement, the catheter and guide wire were withdrawn and the arteriotomy was closed. Follow-up radiographs were obtained immediately after the procedure to document the position of the coil. Aortography was performed *via* percutaneous brachial artery puncture in all 4 dogs 1 week and 4 weeks after coil placement to assess graft patency. During follow-up arteriography, care was taken not to advance a guide wire or catheter through the graft to prevent dislodgement of thrombi. One animal was killed 4 weeks after the procedure and the aorta was examined grossly and histologically.

Results

All grafts were widely patent at 1 week and 4 weeks (Fig. 2). Some narrowing of the original arterial lumen was demonstrated on closely wound coils at 1 week due to fibrin deposition on the coil. However, no progression of the lesions was noted at 4 weeks. In the animal that was killed at 4 weeks, fibrin deposition on the coil was demonstrated grossly and histologically (Fig. 3). None of the animals manifested any ill effects such as fever or gait disturbance after the procedure. Long-term patency studies are underway.

Discussion

This preliminary study demonstrates the feasibility of transcatheter arterial grafting. By using nitinol wire, the two main problems associated with this technique, namely, thrombosis of the endoprosthesis and difficulty in introducing a graft of suitable size through conventional angiographic catheters, appear to be solved.

We found that nitinol coil grafts of varying size and frequency exhibited

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See also the article by Dotter *et al.* (pp. 259-260) in this issue. cg

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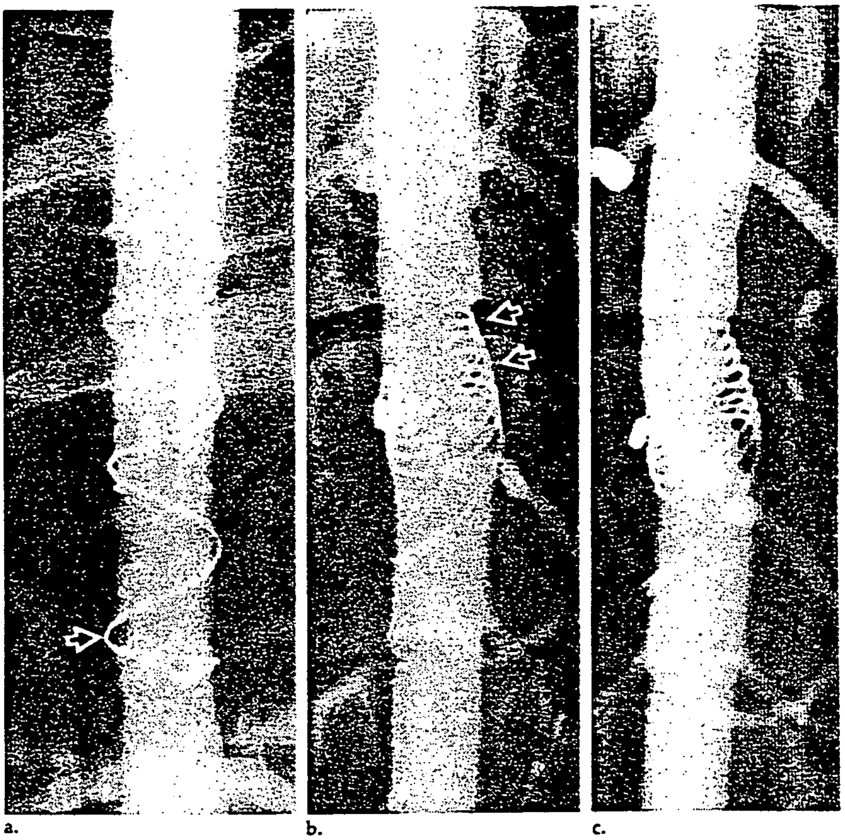
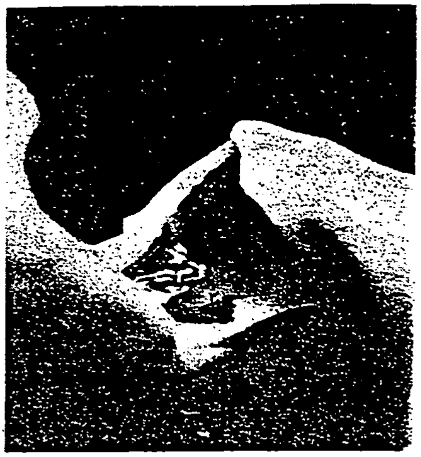
Figure 2



a. Loosely wound coil 1 week after introduction. Wide patency of the graft is demonstrated with minimal thrombus formation (arrow).
b. Closely wound coil 1 week after introduction. The coil lies slightly eccentrically in the artery. Some narrowing of the lumen is demonstrated due to fibrin deposition on the coil (arrows).
c. Same coil 4 weeks after introduction shows no progression of intraluminal fibrin deposition.

Figure 3



Abdominal aorta of a dog 4 weeks after the introduction of a nitinol coil. The coil has been completely covered by fibrin, which decreases the risk of subsequent thrombosis.

little tendency to thrombose. Simon *et al.*, who have developed a percutaneously placed nitinol vena cava filter, obtained similar results (3). It is likely that the coils act similar to a porous graft, allowing ion exchange between the vessel wall and lumen. As in other grafts, the coil serves as a template for formation of new intima, decreasing the risk of complete thrombosis even in long-term implants.

We placed coils of varying frequency to test for thrombogenicity. The two closely wound coils (no space between turns of the coil) showed a slightly greater thrombotic tendency than the two loosely wound coils; however, a widely patent lumen was preserved in both types of coils. None of the animals in our study was heparinized. This finding is encouraging, since dogs are considered to have a more active thrombotic system than humans (4), and it indicates that long-term patency of nitinol coil grafts may be possible in humans.

The unique memory of nitinol wire allows the introduction of a large preformed shape through a relatively small angiographic catheter. At room temperature, the nitinol coil is a straight, pliable wire that can be passed through a catheter. As the coil is extruded from the catheter and warmed to body temperature, it reverts to its "memorized" shape, (*i.e.*, a coil). By regulating the composition of the alloy, the transition temperature of nitinol wire can be adjusted to provide transformation over a narrow temperature range (*e.g.*, 36–38° C). The wire we used in this study transformed over a broad temperature range (25–38° C), which required flushing the introducing catheter with cold saline to minimize transformation of the wire in the catheter. We also used a 10-F Teflon introducing catheter to reduce friction of the partially transformed coil in the catheter. These difficulties can be overcome by the development of a wire with a more precise transition temperature.

We have recently been able to introduce long, closely wound coils into the abdominal aorta (Fig. 4). While long-term patency studies in these types of grafts have not been completed, the ability to introduce closely wound coils of any length does indicate that nonsurgical "replacement" of diseased arteries may be possible.

Potential applications exist for both the closely wound and loosely wound coil grafts. One application might be the nonsurgical treatment of inoperable aortic aneurysms using a closely wound coil graft. It is possible that the coil would endothelialize and provide the structural strength of a synthetic surgical graft. Loosely wound coils could be used as stents to maintain vessel patency. Such a stent may maintain long-term patency of a ductus arteriosus in certain forms of ductus-dependent congenital heart disease. In the venous system, nonsurgical grafting may find application in cases of external venous compression or in the creation of a transhepatic portocaval shunt. Other applications exist for nitinol endoprostheses in both the biliary and urinary tract, where they may provide easier introduction and better patency rates than existing stents.

Further experimental study is needed to assess the biocompatibility and long-term patency of nitinol coil grafts. With the development of a suitable alloy with optimal transformation characteristics, nitinol coil grafts may offer a simple, inexpensive alternative to surgery in numerous forms of cardiovascular disease.

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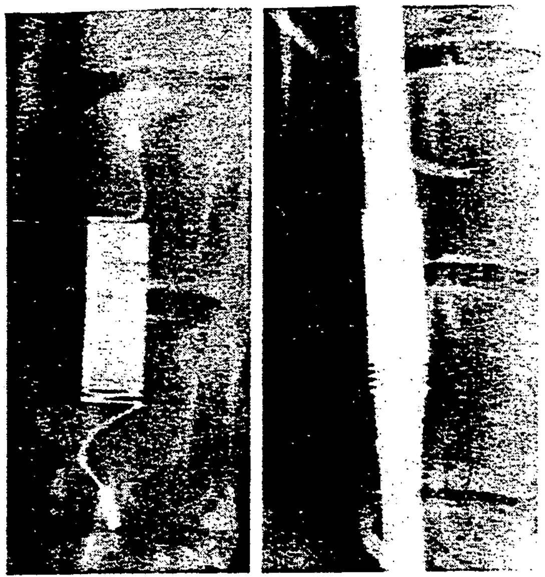
Figure 4



a. b.

a. Closely wound coil (diameter 7 mm, length 4 cm).
b. Abdominal aortogram immediately following introduction. The feasibility of placing very tightly wound coils of significant length is demonstrated.